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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,650	06/13/2006	Petr Dobrovolsky	J187-034 US	1526
27433 7590 07/25/2008 FOLEY & LARDNER LLP 321 NORTH CLARK STREET SUITE 2800 CHICAGO, IL 60610-4764				
EXAMINER				
AULAKH, CHARANJIT				
ART UNIT		PAPER NUMBER		
1625				
MAIL DATE		DELIVERY MODE		
07/25/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/582,650

**Applicant(s)**

DOBROVOLNY, PETR

**Examiner**

Charanjit S. Aulakh

**Art Unit**

1625

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/55/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. According to paper filed on April 14, 2008, the applicants have amended claims 23-35 and furthermore, have added new claims 36 and 37.
2. Claims 23-37 are now pending in the application.

### ***Response to Arguments***

3. Applicant's arguments filed on April 14, 2008 have been fully considered but they are not persuasive regarding obviousness rejection. The applicants have amended claims to overcome indefiniteness rejections. In regard to obviousness rejection, the applicants argue on page 8, second paragraph that the amount of acetic acid used was different in the instant process ( 668 to 1001 mol as compared to the process of Lin ( 197 mol ). However, Lin's reference does not mention this amount at all. It is not clear where the applicants find this amount in Lin's reference. Similarly, Lin's reference is silent about the time of oxidation. The applicant's argue that Wood's reference uses much longer period. However, Wood's reference does not teach oxidation of 7-ethyl-1,2,6,7-tetrahydrocamptothecin and therefore, is irrelevant. Lin clearly demonstrates the beneficial effect of oxidation of 7-alkyl-1,2,6,7-tetrahydrocamptothecin with iodobenzenediacetate in acetic acid/water in order to get 7-alkyl-10-hydroxy-camptothecin in high yield ( see col. 3, lines 30-35 ). The declaration filed by the applicants is also irrelevant at this stage. The priority date of the Lin's reference is May 12, 2003 whereas the effective filing date of the instant application is 16 Dec. 2003 and therefore, Lin's reference does qualify as a prior art reference. On the other hand, once all the issues are resolved and an interference is declared with Lin's patented claims (

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claims 2-12 ), only then this declaration will be needed. Also, the applicants need to clarify regarding the structure of 7-ethyl-1,2,6,7-tetrahydrocamptothecin since according to Lin's reference, 7-ethyl-1,2,6,7-tetrahydrocamptothecin ( formula II in column 2, lines 40-48 ) has a double bond present between C6 and C7 whereas it is absent in the instant compounds of formula (IV).

### ***Conclusion***

4. Rejection of claims 23-37 under 35 U.S.C. 103(a) over Lin's reference is maintained for the reasons of record.

### **NEW GROUNDS OF REJECTION**

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 23 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 23, the amount of acetic used is listed as 1130 mol per 1 mol of 7-ethyl-1,2,6,7-tetrahydrocamptothecin. This introduces new matter since according to the specification, this amount can only be 668 to 1001 mol ( see page 4, line 10 ). Similarly, in claim 36, the amount of iodobenzenediacetate

used is listed as 1.9 mol. However, according to the specification, this amount can only be ) 0.99 to 1.85 mol ( see page 4, line 13 ). This also introduces new matter.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571)272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charanjit S. Aulakh/  
Primary Examiner, Art Unit 1625